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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/998,961      | 10/31/2001  | E. Skott Greenhalgh  | 24491-A USA         | 6493             |

7590

03/10/2004

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EXAMINER

LANDREM, KAMRIN R

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

3738

DATE MAILED: 03/10/2004

5

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/998,961

Applicant(s)

GREENHALGH, E. SKOTT

Examiner

Kamrin R. Landrem

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 24 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,5,7-11 and 13-31 is/are pending in the application.
- 4a) Of the above claim(s) 21-29 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,5,7-11,13-20, and 30,31 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 31 October 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input checked="" type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

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**DETAILED ACTION**

***Allowable Subject Matter***

The indicated allowability of claim 6-9, 11-15, and 17-20 is withdrawn in view of the newly discovered reference(s) to Lazarus (USPN 5,693,088). Rejections based on the newly cited reference(s) follow.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 5, 8, 9, 30, 31 are rejected under 35 U.S.C. 102(b) as being anticipated by Lazarus (USPN 5,693,007).

With reference to Figures 1 and 2, Lazarus discloses a bifurcated graft compatible with living animal tissue said graft comprising an elastic polytetrafluoroethylene elongated tubular substrate having attachment regions 16 positioned at each end, a plurality of pores extending through said attachment region to promote ingrowth and to sealingly attach said substrate to adjacent tissue (5:36-40) thereby making portions between said attachment regions substantially impermeable to fluids (2:47-57). The attachment regions are coated with a substance that promotes healing, such as a collagen material (13:25-46). The attachment regions can be composed of a second material different from that of the other portions of the graft. The second

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material, such as polypropylene (5:54+) may be used to elicit a healing response from the living tissue.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 10 and 14-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lazarus in view of Lentz et al (USPN 6,428,571).

Lazarus, as discussed above, discloses the compatible graft as claimed. Lazarus however fails to disclose that the graft can be disclosed of a non-woven ePTFE material. Lentz teaches a vascular graft composed of expanded polytetrafluoroethylene that is defined of elongate fibrils interconnected that create varying degrees of porosity to provide enhanced endothelialization due to regions of higher porosity and enhanced strength due to the regions of lower porosity(4:34-52). Therefore in view of the teachings it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the compatible graft disclosed by Lentz to incorporate the ePTFE material as taught by Lentz in order to produce a graft with varying degrees of porosity for improved structural properties and increased tissue ingrowth.

Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lazarus in view of Chouinard (USPN 6,156,064).

Lazarus, as discussed above, discloses the compatible graft as claimed. Lazarus however fails to disclose that the specific permeability of the compatible graft. Chouinard teaches a

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compatible PTFE or ePTFE (3:50) that has a permeability range of 50 cc/cm<sup>2</sup>/min to about 5000 cc/cm<sup>2</sup>/min to create a graft with an impermeable layer and an permeable layer (1:10-15).

Therefore in view of the teachings it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the graft disclosed by Lazarus to incorporate the specific permabilities as taught by Chouinard to produce a graft with regions that are permeable for tissue ingrowth and areas that are impermeable to fluids and tissue to restore flow.

Claims 11,13, and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lazarus as modified by Lentz, further in view of Karwoski et al (USPN 6,042,666).

Lazarus, as discussed above, discloses the compatible graft as claimed. Lazarus however fails to disclose the specific pore size of the compatible graft. Karwoski teaches an endovascular graft with regions that have different pore size (50-500 microns), pore shape and porosity (3:21-53) to produce areas of greater porosity to serve as a microscaffolding structure fore growth of connective tissue and an area having smaller pore structure for reconstituting a biological flow surface through the vessel (3:66-4:4:11). While Karwoski does not specifically recite that the pores are pierced it is inherent that the product formed would have the same end resulting pore size. Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. (See MPEP 2113). Therefore in view of the teachings it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the graft disclosed by Lazarus to incorporate the various pore sizes taught by

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<sup>u)</sup> Karwoski in order to produce a graft with portions that promote ingrowth and areas that are impermeable and promote blood flow.

### ***Response to Arguments***

Applicant's arguments filed November 24, 2003 have been fully considered but they are not persuasive.

Applicant's election with traverse of Species A and sub-species a (Figures 2 and 3) in Paper No. 4 is acknowledged. The traversal is on the ground(s) that there would not be a serious burden on the Examiner if all pending claims were searched. This is not found persuasive because there are several embodiments present in the claims. The embodiment shown in Figures 4 and 5 have a textured surface with loops as opposed to the porous surface shown in the embodiments in Figures 2 and 3.

The requirement is still deemed proper and is therefore made FINAL.

Applicant's arguments with respect to claims 1-31 have been considered but are moot in view of the new ground(s) of rejection.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kamrin R. Landrem whose telephone number is 703-305-8061. The examiner can normally be reached on 8:00-5:00, Monday-Friday.

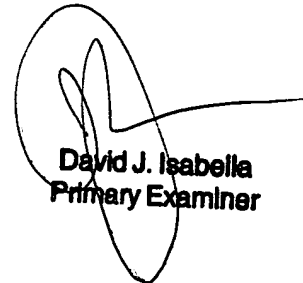
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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 703-308-2111. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Kamrin Landrem  
Examiner  
AU 3738

KRL



David J. Isabella  
Primary Examiner